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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,666	06/20/2007	Dan Rottenberg	372/05298	4703

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EXAMINER	
SU, SUSAN SHAN	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,666	ROTTENBERG ET AL.	
	Examiner	Art Unit	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-12 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-6, 9-12, & 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The finality of the previous Office Action is withdrawn in view of the new grounds of rejection raised herein. New prior art is found to suggest the claim limitations that were previously determined to be allowable subject matter. The instant Office Action is thus made Non-Final.

Status of Claims

Claims 1, 3-6, 9-12, and 15-19 are pending and examined on the merits.

Claim Objections

1. Claims 1, 10, 11, & 17 are objected to because of the following informalities: lack of antecedent basis. For Claims 1, 10, & 11: there is no mention of a structure called "cover," thus it is suggested that "said cover" be changed to --said flow regulating mechanism--. For Claim 17, "in said body" should be removed since there is no recitation of "a body" prior to that and "said chambers" should be changed to --said atria--. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1, 10, and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the instant case, when the claims recite a device or an apparatus with certain elements being "attached to" to the human body or specific body parts, the claim language "positioned in the septum of a heart" positively sets forth a claim on the human body, which makes it non-statutory

subject matter. It is suggested that the language be changed to the format "adapted to be positioned" or "for positioning" or in similar ways which does not positively claim the body part.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3-4, 9-10, 17, & 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. (US 2004/0147869, "Ref. 1").

With regard to Claim 1, Ref. 1 teaches a differential pressure regulating device (see Figs. 6F & 8E), the device comprising:

a shunt (720) adapted to be positioned in the heart to enable fluids to flow between two chambers and an adjustable flow regulating mechanism (e.g. 732) being configured to selectively cover an opening of said shunt while keeping said cover always ajar, to regulate and keep the flow of fluid

through said shunt in relation to a pressure difference between said chambers.

Ref. 1 does not specifically teach that the two chambers are the left and right atria. However, Ref. 1 discloses that the heart wall can be the septum (which is between the two ventricles or the two atria, see [0112]) of the heart. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ref. 1 to ease the pressure on the diseased chamber of the heart.

With regard to Claims 3 & 4, Ref. 1 also teaches that the flow regulating mechanism is to be continually adjustable in accordance with at least one pressure threshold or in accordance with changes in pressure difference between said chambers ([0134] where cardiac cycle naturally causes pressure differences).

With regard to Claim 9, Ref. 1 also teaches that the flow regulating mechanism is to close the opening of said shunt ([0134-0135]).

With regard to Claim 10, Ref. 1 teaches all the limitations that are repeated in Claim 1 and that the flow regulating mechanism includes one or more mechanisms selected from the group consisting of a disk valve connected to a twisting spring, a pre-shaped flexible wire, a cone connected to a compression spring, a leaflet valve (see Fig. 6F), a flexible disk having an adjustable, substantially central hole, a first balloon having liquid therein and connected through a tube to a second balloon, a first balloon having liquid therein and connected through a tube to a reservoir having a piston moving against a compression spring, and a first balloon having liquid therein and connected

through a tube to a reservoir having a piston moving in accordance with a controlled activation system.

With regard to Claim 17, Ref. 1 teaches an in-vivo pressure control method the method comprising:

implanting (see Abstract) a differential pressure regulation device including a shunt in the heart wall between two chambers;

deploying a flow regulating mechanism (Abstract),

controlling a setting of said flow regulating mechanism according to changes in pressure differences between said chambers ([0134]), and

maintaining a flow between said chambers through all pressure differences between said chambers (with the fact that the valve never closes completely).

Ref. 1 does not teach that the two chambers are the left and right atria. However, Ref. 1 discloses that the heart wall can be the septum ([0112]) of the heart. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ref. 1 to ease the pressure on the diseased chamber of the heart.

With regard to Claim 19, Ref. 1 also teaches reducing a pressure difference between the two chambers (when blood is free to flow between the chambers the pressure difference is reduced).

7. Claims 5-6, 11-12, 15-16, & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ref. 1 as applied to claim 1 above, and further in view of Wolf et al. (US 2002/0165606, "Ref. 2").

With regard to Claims 5-6 & 11-12, Ref. 1 does not teach expressly a control mechanism for remote control of the flow regulating mechanism. Ref. 2 teaches a control mechanism (30 & 36, Fig. 7) to remotely control said flow regulating mechanism (the sensors 30 are placed away from the flow regulating mechanism 10) wherein the control mechanism includes one or more mechanisms selected from the group consisting of wires, lines, springs, pins, cables, magnets, hooks, latches, electric mechanisms (30), pressure transducers, telemetry mechanisms, wireless mechanisms, pneumatic mechanisms, and motors. It would have been obvious to modify Ref. 1 with Ref. 2 for the purpose of being actively control the opening and closing of the valve.

With regard to Claim 15, Ref. 1 also teaches that the flow regulating mechanism is to be continually adjustable in accordance with at least one pressure threshold ([0134]).

With regard to Claim 16, Ref. 1 does not teach that the flow regulating mechanism is rigid. Ref. 2 teaches that the flow regulating mechanism is rigid ([0041] and [0045] where valve 16 of Fig. 7 made of the same material as shunt 12) and its position is directly controlled by the control mechanism, thereby substantially determining the precise size of the opening of the shunt. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ref. 1 with Ref. 2 with a rigid valve for the purpose of having the option of determining the flow volume between the two chambers independent of the pressure threshold.

With regard to Claim 18, Ref. 1 does not teach remotely controlling the flow regulating mechanism positioning. Ref. 2 teaches remotely controlling the flow

regulating mechanism positioning ([0050]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ref. 1 with Ref. 2 for the purpose of determining the flow volume between the two chambers independent of the pressure threshold.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wilk (US 7,294,115), Tweden et al. (US 2004/0077988) teach a shunt in the heart wall similar to the above references. Akin et al. (US 2003/0100920) teaches a shunt with a valve element connecting two parallel vessels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761